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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/762,476 | 09/27/2001 | Michael Mendez | 40977 | 5080 |
| 7590 | 06/30/2004 | | EXAMINER | AKHAVAN, RAMIN |
| Steven B. Kelber, Esq. Piper Rudnick, LLP 1200 19th Street N.W. Washington, DC 20036 | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Applicant 06/28/04 RA

| Office Action Summary | Application No. | Applicant(s) |
|-----------------------|---------------------|---------------|
| | 09/762,476 | MENDEZ ET AL. |
| | Examiner | Art Unit |
| | Ramin (Ray) Akhavan | 1636 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 April 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 7-13 and 32 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 7-13 and 32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment filed, 04/13/2004, is acknowledged and entered. Pursuant to the amendment, claims 1-6, 14-31 and 33-47 are cancelled and claim 7 amended. Claims 7-13 and 32 are pending and under consideration in this action. All objections and rejections not repeated herein are withdrawn. This action is *not* final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1. Claim 7-8 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The base claim recites the term “vector system” which implies method steps. Furthermore, it is unclear if there actually any vectors in this “vector system”. For example, is the claim to be interpreted to mean that each “arm” or even both “arms” are on a vector? Given the ambiguity and lack of clarity, the claim’s metes and bounds are indefinite.

Claim 7 recites the limitation “said target nucleotide”. There is insufficient antecedent basis for this limitation in the claim. The term should be “said target polynucleotide”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the new rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 7-8 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (US 5,348,886; see whole document; hereinafter ‘886 patent).

The claims are drawn to a vector system for cloning large nucleic acids and delivery of the cloned nucleic acid to a target cell, where the composition comprises a first arm with a first selectable marker, a first cyclization element and a first segment homologous to the 5' terminus of a target polynucleotide and a second arm with a second selectable marker, second cyclization element and second segment homologous to the 3' terminus of the target polynucleotide, wherein the target nucleic acid is a virus, particularly DNA virus, more particularly a DNA virus such as adenovirus. The limitation of “first” and “second arm” is interpreted as broadly as reasonable. Therefore the arms could for example be different regions of a circular or linear vector or construct.

The ‘886 patent teaches a composition comprising viral DNA, a first region (i.e. arm) containing a first genetic marker (i.e. selectable marker; e.g. β-gluc), a preferential target site for insertion of a transposon (i.e. cyclization element; e.g. attTn7-phoS), a second genetic marker (e.g. Amp) and a second specific insertion site (i.e. cyclization element; e.g. attTn7-glmS). (e.g. col. 3, ll. 20-35; col. 5, ll. 35-40; Fig. 4). The ‘886 patent teaches, that the composition can comprise viral DNA. (e.g. col. 3, ll. 20-24; Fig. 4). As such parts of this viral DNA could

intrinsically be construed as part of the first and second arm. Furthermore, these particular regions, being part of a contiguous fragment of viral DNA, would have homologous regions to 5' and 3' ends of a corresponding piece of viral DNA. In addition, *E. coli* is taught as containing the composition. (e.g. col. 16, ll. 65-68, bridging to col. 17, ll. 1-5). In sum, the '886 patent anticipates the rejected claims.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 7-13 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 5,348,886; see whole document; hereinafter '886 patent).

The claims are drawn to composition and bacterial cells comprising the same, where the vector system comprises two arms each comprising a selection marker, a cyclization element and

regions that are homologous to 5' and 3' termini of viral DNA. More particular claims are drawn to the viral DNA being DNA virus, for example adenovirus, or RNA virus, particularly RNA virus, more particularly retrovirus, lentivirus or human immunodeficiency virus (HIV).

The '886 patent does not teach the particular DNA or RNA viruses. (*see supra*, § 102(b) Rejection No. 1 for what '886 teaches).

However, the '886 patent explicitly teaches that heterologous DNA comprised in the vector system can be from any source. (e.g. col. 6, l. 5). Therefore, it would have been obvious to use viral DNA from various species.

One of ordinary skill in the art would be motivated to substitute any viral piece of DNA in the vector system, so as to expand the range of species manipulated using the vector system taught. Given the knowledge and skill at the time of the invention, with regard to the species of viruses known in the art, there would have been a reasonable expectation of success in substituting the heterologous DNA system with viral DNA from DNA or RNA viruses, as well as from adenovirus, lentivirus and HIV.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday- Friday from 8:00-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can

be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


GERRY LEFFERS
PRIMARY EXAMINER